

REMARKS/ARGUMENTS

Claims 1-2, 4-16, 18-30, 57-58 are pending. Claims 3, 4, 17, and 31-56 are cancelled.

Claims 1 and 2 have been amended to recite that the host cell includes an  $\alpha$ -1,2-mannosidase activity and a GlcNAc transferase I (GnT I) activity and is diminished or depleted in the activity of an initiating  $\alpha$ -1,6-mannosyltransferase and which produces N-glycans comprising  $\text{Man}_5\text{GlcNAc}_2$  or  $\text{GlcNAcMan}_5\text{GlcNAc}_2$  structures, the method comprising the step of expressing in the host cell a nucleic acid encoding a mannosidase enzyme that is capable of hydrolyzing *in vivo* an oligosaccharide substrate comprising either or both a  $\text{Man}\alpha 1,3$  and  $\text{Man}\alpha 1,6$  glycosidic linkage to the extent that at least 10% of the  $\text{Man}\alpha 1,3$  and/or  $\text{Man}\alpha 1,6$  linkages of the substrate are hydrolyzed *in vivo*, whereby expression of said mannosidase produces one or more desired N-glycan structures on a recombinant glycoprotein expressed in said host cell wherein the desired N-glycan is characterized as having at least the oligosaccharide branch  $\text{Man}\alpha 1,3$  ( $\text{Man}\alpha 1,6$ )  $\text{Man}\beta 1,4$ -GlcNAc  $\beta 1,4$ -GlcNAc-Asn.

Support for the above amendments to Claims 1 and 2 can be found throughout the specification. For example, support for the phrase "wherein the desired N-glycan is characterized as having at least the oligosaccharide branch  $\text{Man}\alpha 1,3$  ( $\text{Man}\alpha 1,6$ )  $\text{Man}\beta 1,4$ -GlcNAc  $\beta 1,4$ -GlcNAc-Asn" can be found in cancelled claim 4 and in paragraph [0058] of the published application. Support for host cells including an  $\alpha$ -1,2-mannosidase activity and a GlcNAc transferase I (GnT I) activity and is diminished or depleted in the activity of an initiating  $\alpha$ -1,6-mannosyltransferase and which produces N-glycans comprising  $\text{GlcNAcMan}_5\text{GlcNAc}_2$  structures can be found Figure 13 and in Example 17. Additional support can be found in the discussion of libraries beginning with paragraph [0585] on page 96; paragraph [0676] on page 138.

I. Claims 1, 2, 5, 7, 9, 16, 18-22, 24-30, 57, and 58 stand rejected under 35 U.S.C. § 102(e).

Claims 1, 2, 5, 7, 9, 16, 18-22, 24-30, 57, and 58 were rejected under 35 U.S.C. § 102(e) as being anticipated by US 7,029,872 to Gerngross. Independent Claims 1 and 2 have been amended to include the limitation of Claim 4, which according to the instant Office Action is not anticipated by Gerngross. Therefore, currently amended Claims 1 and 2 and their

Application No.: 10/616,082  
Amendment Date: 8-Feb-08  
Reply to Office Action of: 10 Sept. 07

dependent claims are not believed to be anticipated by Gerngross. In light of the amendments to Claims 1 and 2, reconsideration of the rejection is requested.

II. Claims 1-2, 4-16, 18-30, and 57-58 stand rejected under 35 U.S.C. § 112, first paragraph.

Claims 1-2, 4-16, and 18-30 were rejected under 35 U.S.C. § 112, first paragraph, for not being enabled for GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub>.

The applicant believes that the currently amended claims satisfy 37 U.S.C. § 112. Claim 1 has been amended to recite that the uni- or multicellular fungal host cell includes an α-1,2-mannosidase activity and a GlcNAc transferase I (GnT I) activity. Thus the host cells include all of the enzymatic activities needed to enable it to produce GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> which is supported throughout the application and specifically, for example, by the Example 17 and Figure 13. In light of the amendment, reconsideration of the rejection is requested.

CONDITIONAL PETITION

Applicant hereby makes a Conditional Petition for any relief available to correct any defect in connection with this filing, or any defect remaining in this application after this filing. The Commissioner is authorized to charge deposit account 13-2755 for the petition fee and any other fee(s) required to effect this Conditional Petition.

Respectfully submitted,

By

John David Reilly  
Reg. No. 43,039  
Attorney for Applicant

MERCK & CO., INC.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
(732) 594-6914

Date: Feb 8, 2008